MAY 1 6 2000

510 (k) SUMMARY

K001169

COMPANY NAME AND ADDRESS

Optimize Inc.
420 Blossom Hill Road
Los Gatos, CA 95032

Tel: 408-358-0900
Fax: 408-358-0901

CONTACT PERSON

Kenneth Gong
Director of Quality Assurance

Tel: 408-358-0925
E-Mail: www.kgong@optivu.com

DEVICE TRADE NAME

OptiVu System

COMMON NAME

Viewing Monitor

CLASSIFICATION NAME

Endoscope and accessories (per 21 CFR 876.1500)

PREDICATE DEVICES

1)	Device Name:	Sony Trinitron color video monitor PVM-1343MD
	Manufacturer:	Sony Medical Electronics Co. 42 West Stret, Suite 2 Attleboro. MA 02703
	510K #:	K885042
	Regulation #	878.4160
	Product code:	KQM
2)	Device Name:	Head Mounted Display
	Classification:	Class II
	Manufacturer:	Vista Medical Technologies 5451 Avenida Encinas, Suite A Carlsbad, CA 92008
	510K #:	K961800
	Regulation #	876.1500
	Product code:	GCJ

3)	Device Name:	Personal Monitor
	Classification:	Class II
	Manufacturer:	Med Vision Inc. 257 Kempsey Drive North Brunswick, NJ 08902
	510K #:	K961343
	Regulation #	876.1500
	Product code:	GCJ

4)	Device Name:	Vitacomm Model 100 Esophageal Stethoscope
	Classification:	Espohageal stethoscope with electrical conductors
	Manufacturer:	Vitacomm, Inc. 2165 N. Glassell Street Orange, CA 92665
	510(k) #:	K842309
	Regulation #	868.1920
	Product code:	BZT

DESCRIPTION OF THE DEVICE

The OptiVu System is a head mounted monocular (2D) video display, which is intended for use as part of a visualization system in minimally invasive surgery. The OptiVu system accepts and processes NTSC or PAL standard video signals in composite video, Y/C (S video) or RGBSync formats and displays the video signal on a solid state display device, called Liquid Crystal On Silicone (LCOS).

Optionally, the OptiVu System may include wireless video and two way audio capabilities based on infrared (IR) technology. The system consists of one or more headsets, one base station (control unit), and as an option one or more of the following components: a ceiling or pole mounted transmitter/receiver (IRT), headset battery and battery charging system.

INTENDED USE

The intended use of the OptiVu System is to display video images while mounted in front of the user's eyes.

COMPARISON WITH PREDICATE DEVICE

The OptiVu system is similar to the Vista HMD (Head Mounted Display) which received FDA clearance on September 11,1996 (K961800) and the Med Vision Personal Monitor which received FDA clearance on March 13, 1997 (K961343). Both these devices accepts standard video signals (NTSC or PAL) from an endoscopic camera and displays the image on LCD (Liquid Crystal Display) screens mounted on the users head.

The optional wireless capability of the OptiVu System is substantially equivalent to the Vitacomm Model 100 Esophageal Stethoscope and Vital Signs Monitor (ESVSM) which received FDA clearance on June 18, 1984. The Vitacomm Model 100 ESVSM uses infrared light to transmit patient vital signs to a receiver worn by the physician. The Model 100 is powered by a rechargeable battery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2000

Optimize, Inc.
c/o Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K001169
Trade Name: OptiVu HDVD System
Regulatory Class: II
Product Code: GCJ
Dated: May 1, 2000
Received: May 2, 2000

Dear Mr. Sherratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K _____

Indications for use statement

510(k) Number (if known): K001169

Device Name: OptiVu HDVD System

Indications For Use: Original contained within the 510(k) submission

The OptiVu HDVD system is intended to display video images while mounted in front of the users eyes

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Anne R. Lachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001169